DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2014

Teleflex Medical, Inc.
Mr. James A. Cochie
Sr. Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K141353
Trade/Device Name: Hudson RCI® AquaPak® Prefilled Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: June 30, 2014
Received: July 2, 2014

Dear Mr. Cochie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141353

Device Name
Hudson RCI® AquaPak® Prefilled Humidifier

Indications for Use *(Describe)*
The Hudson RCI® AquaPak® Prefilled Humidifier adds humidity to a patient's breathing gases.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Section 24 – 510(k) Summary

510(k) SUMMARY

Hudson RCI® AquaPak® Prefilled Humidifiers

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8083
Fax: 919-433-4996

B. Contact Person

James Cochie
Sr. Regulatory Affairs Specialist

C. Date Prepared

July 31, 2014

D. Device Name

Trade Name: Hudson RCI® AquaPak® Prefilled Humidifier

Common Name: Humidifier

Classification Name: Humidifier, Respiratory Gas (Direct Patient Interface), CFR – 868.5450, Class II

E. Device Description

Hudson RCI® AquaPak® Prefilled Humidifiers add water vapor (molecular H_2O) to a dry medical gas that is suspended in the gas to be inhaled by the patient.

The Hudson RCI® AquaPak® Prefilled Humidifiers are designed to add humidity to inspired gas, helping to control the drying and irritation of the respiratory mucosa. The humidifiers feature a micro-diffuser that produces smaller bubbles and greater surface agitation, allowing for a quiet operation and therapeutic humidity output.

Prefilled sterile reservoirs for AquaPak® Humidifiers come in four sizes; 190ml, 340ml, 540ml and 650ml. Each reservoir must be used with a suitable adaptor component, which connects the system to a flow-metered gas source and provides humidifier functionality.

Section 24 – 510(k) Summary

Adaptor types provided with Hudson RCI® AquaPak® Prefilled Humidifiers feature an audible pressure relief valve, which indicates a restriction of gas flow to the user.

F. Indications for Use

The **Hudson RCI® AquaPak® Prefilled Humidifier** adds humidity to a patient's breathing gases.

G. Target Population

This device is intended for use on any patient connected to ventilation devices

H. Environments of Use

This device is intended for hospital, sub-acute facilities, long-term care facilities and in a home care environment.

This product is single use only.

I. Contraindications

There are no known contraindications.

J. Comparative Characteristics

The proposed **Hudson RCI® AquaPak® Prefilled Humidifier** is substantially equivalent to the predicate device:

Comparative Characteristics	Proposed Device: Hudson RCI® AquaPak® Prefilled Humidifier	Predicate Device: Hudson RCI® AquaPak® Prefilled Humidifier	Predicate Device: CareFusion Airlife® Prefilled Humidifier
Manufacturer	**Teleflex Medical, Inc.**	**Teleflex Medical, Inc.**	**CareFusion**
510(k) Number	**TBD**	**K780562 – Prefilled Humidifier K833974 – Humidifier Adaptor**	**K853146**
Indications for Use	**The Hudson RCI® AquaPak® Prefilled Humidifier adds humidity to a patient's breathing gases.**	**The Hudson RCI® AquaPak® Prefilled Humidifier adds humidity to a patient's breathing gases.**	**The CareFusion Airlife® Prefilled Humidifiers provide a cost-effective solution for sterile water inhalation.**

Section 24 – 510(k) Summary

			(www.caefusion.com)
Principle of Operation	**Gas bubbles through built-in diffuser in reservoir**	**Gas bubbles through built-in diffuser in reservoir**	**Gas bubbles through reservoir**
Gas source	**50 Psi oxygen regulated via a flow meter**	**50 Psi oxygen regulated via a flow meter**	**50 Psi oxygen regulated via a flow meter**
Technology and Features	**Flow rate: 1.5 – 10 LPM** **Audible notification of occlusion: 5 – 30 psi** **Humidity output: At least 10mg H_2O/L**	**Flow rate: 1.5 – 10 LPM** **Audible notification of occlusion: 5 – 30 psi** **Humidity output: At least 10mg H_2O/L**	**Flow rate: 4 LPM for audible notification** **Audible notification of occlusion: Not specified** **Humidity output: Not specified**
Sterilization	**Adaptor – Non-sterile** **Sterile Water/Saline Reservoirs - Reverse osmosis, distillation, and aseptic fill**	**Adaptor – Gamma Irradiation** **Sterile Water/Saline Reservoirs - Reverse osmosis, distillation, and aseptic fill**	**Adaptor – Non-sterile** **Sterile Water/Saline Reservoirs – Steam or dry heat**
Single Use	**Yes**	**Yes**	**Adaptor – Single Patient Use** **Sterile Water/Saline Reservoirs – Single Use**
Shelf Life	**Adaptors – N/A** **Sterile Water/Saline – 2 years from date of manufacture**	**Adaptors – 5 years from date of manufacture** **Sterile Water/Saline – 2 years from date of manufacture**	**Adaptors – N/A** **Sterile Water/Saline – 2 years from date of manufacture**
Packaging	**Adaptor Top web: Coated High Density Polyethylene (HDPE)** **Adaptor Bottom web: Surlyn Amcor C-060**	**Adaptor Top web: Tyvek** **Adaptor Bottom film: Surlyn Amcor C-060** **Bottle – Sealed**	**Adaptor – Heat sealed polybag** **Bottle – Sealed polypropylene**

	Bottle – Sealed polypropylene	**polypropylene**	

K. Non-clinical Comparative Performance Testing

Bench testing has been performed to verify that the performance of the proposed **Hudson RCI® AquaPak® Prefilled Humidifier** is substantially equivalent to the predicate device, and that the **Hudson RCI® AquaPak® Prefilled Humidifier** will perform as intended.

Test Performed	Reference to Standard (if applicable)	Principle of Test
Packaging Integrity Tests	ISTA 2A	Determines the integrity of the packaged device against known shipping tests
Ink Adherence Tests	ASTM F2252	Determines ink adherence properties of the printed film used in packaging the device
Cannula Pop-Off, Bottle Burst, Occlusion Test	N/A	Determines strength of the tubing connector, the reservoir does not burst when nares are occluded and the relieve valve performs as expected to relieve pressure
Spitting Test	N/A	Determines the expected outcome that the humidifier will not spit or flood the tubing at the maximum flow rate of 10 LPM
Humidification Output Test	N/A	Determines the rate of humidification at which the liquid is humidified and emitted in milligrams per liter

L. Substantial Equivalence

The proposed **Hudson RCI® AquaPak® Prefilled Humidifier** is substantially equivalent in intended use, design, performance and principles of operation to the identified predicate devices cleared under 510(k) K780562 and K833974. The differences between the proposed **Hudson RCI® AquaPak® Prefilled Humidifier** and the predicate devices are minor (sterile to non-sterile packaging) and raise no new issues of safety and efficacy. The proposed **Hudson RCI® AquaPak® Prefilled Humidifier** is substantially equivalent to the currently marketed predicate devices.